



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0007]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2015

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates and payment procedures for fiscal year (FY) 2015 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Animal Drug User Fee Amendments of 2013 (ADUFA III), authorizes FDA to collect user fees for certain animal drug applications and supplements, for certain animal drug products, for certain establishments where such products are made, and for certain sponsors of such animal drug applications and/or investigational animal drug submissions. This document establishes the fee rates for FY 2015.

FOR FURTHER INFORMATION CONTACT: Visit FDA's Web site at

<http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm> or

contact Lisa Kable, Center for Veterinary Medicine (HFV-10), Food and Drug Administration, 7529 Standish Pl., Rockville, MD 20855, 240-276-9718. For general questions, you may also email the Center for Veterinary Medicine (CVM) at: [cvmadufa@fda.hhs.gov](mailto:cvmadufa@fda.hhs.gov).

SUPPLEMENTARY INFORMATION:

I. Background

Section 740 of the FD&C Act (21 U.S.C. 379j-12) establishes four different types of user fees: (1) Fees for certain types of animal drug applications and supplements; (2) annual fees for

certain animal drug products; (3) annual fees for certain establishments where such products are made; and (4) annual fees for certain sponsors of animal drug applications and/or investigational animal drug submissions (21 U.S.C. 379j-12(a)). When certain conditions are met, FDA will waive or reduce fees (21 U.S.C. 379j-12(d)).

For FY 2014 through FY 2018, the FD&C Act establishes aggregate yearly base revenue amounts for each fiscal year (21 U.S.C. 379j-12(b)(1)). Base revenue amounts established for years after FY 2014 are subject to adjustment for inflation and workload (21 U.S.C. 379j-12(c)). Fees for applications, establishments, products, and sponsors are to be established each year by FDA so that the percentages of the total revenue that is derived from each type of user fee will be as follows: Revenue from application fees shall be 20 percent of total fee revenue; revenue from product fees shall be 27 percent of total fee revenue; revenue from establishment fees shall be 26 percent of total fee revenue; and revenue from sponsor fees shall be 27 percent of total fee revenue (21 U.S.C. 379j-12(b)(2)).

For FY 2015, the animal drug user fee rates are: \$400,600 for an animal drug application; \$200,300 for a supplemental animal drug application for which safety or effectiveness data are required and for an animal drug application subject to the criteria set forth in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); \$8,075 for an annual product fee; \$104,150 for an annual establishment fee; and \$94,450 for an annual sponsor fee. FDA will issue invoices for FY 2015 product, establishment, and sponsor fees by December 31, 2014, and payment will be due by January 31, 2015. The application fee rates are effective for applications submitted on or after October 1, 2014, and will remain in effect through September 30, 2015. Applications will not be accepted for review until FDA has received full payment of application fees and any other animal drug user fees owed under ADUFA.

## II. Revenue Amount for FY 2015

### A. Statutory Fee Revenue Amounts

ADUFA III (Title I of Public Law 113-14) specifies that the aggregate fee revenue amount for FY 2015 for all animal drug user fee categories is \$21,600,000. (21 U.S.C. 379j-12(b)(1)(B).)

### B. Inflation Adjustment to Fee Revenue Amount

The fee revenue amount established in ADUFA III for FY 2015 and subsequent years are subject to an inflation adjustment (21 U.S.C. 379j-12(c)(2)).

The component of the inflation adjustment for payroll costs shall be 1 plus the average annual percent change in the cost of all personnel compensation and benefits (PC&B) paid per full-time equivalent position (FTE) at FDA for the first three of the four preceding fiscal years, multiplied by the proportion of PC&B costs to total FDA costs for the first three of the preceding four fiscal years (see 21 U.S.C. 379j-12(c)(2)(B)). The data on total PC&B paid and numbers of FTE paid, from which the average cost per FTE can be derived, are published in FDA's Justification of Estimates for Appropriations Committees.

Table 1 summarizes that actual cost and FTE data for the specified fiscal years, and provides the percent change from the previous fiscal year and the average percent change over the first three of the four fiscal years preceding FY 2015. The 3-year average is 1.8829 percent.

Table 1.--FDA Personnel Compensation and Benefits (PC&B) Each Year and Percent Change

Fiscal Year	2011	2012	2013	3-Year Average
Total PC&B	\$1,761,655,000	\$1,824,703,000	\$1,927,703,000	
Total FTE	13,331	13,382	13,974	
PC&B per FTE	\$132,147	\$136,355	\$137,949	
Percent Change from Previous Year	1.2954%	3.1843%	1.169%	1.8829%

The statute specifies that this 1.8829 percent should be multiplied by the proportion of PC&B costs to total FDA costs. Table 2 shows the amount of PC&B and the total amount obligated by FDA for the same three fiscal years.

Table 2.--Personnel Compensation and Benefits (PC&B) as a Percent of Total Costs at FDA

Fiscal Year	2011	2012	2013	3-Year Average
Total PC&B	\$1,761,655,000	\$1,824,703,000	\$1,927,703,000	
Total Costs	\$3,333,407,000	\$3,550,496,000	\$4,151,343,000	
PC&B Percent	52.8485%	51.3929%	46.4356%	50.2257%

The payroll adjustment is 1.8829 percent multiplied by 50.2257 percent (or .9457 percent).

The statute specifies that the portion of the inflation adjustment for non-payroll costs for FY 2015 is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC-MD-VA-WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total FDA costs (see 21 U.S.C. 379j-12(c)(2)(C)). Table 3 provides the summary data for the percent change in the specified CPI for the Baltimore-Washington area. The data from the Bureau of Labor Statistics is shown in Table 3.

Table 3.--Annual and 3-Year Average Percent Change in Baltimore-Washington Area CPI Less Food and Energy

Year	2011	2012	2013	3-Year Average
Annual CPI	140.963	144.413	146.953	
Annual Percent Change	2.2694%	2.4475%	1.7588%	2.1586%

To calculate the inflation adjustment for non-pay costs, we multiply the 2.1586 percent by the proportion of all costs other than PC&B to total FDA costs. Since 50.2257 percent was obligated for PC&B as shown in Table 2, 49.7743 percent is the portion of costs other than PC&B ( $100\% - 50.2257\% = 49.7743\%$  percent). The non-payroll adjustment is 2.1586 percent times 49.7743 percent, or 1.0744 percent.

To complete the inflation adjustment, we add the payroll component (0.9457 percent) to the non-pay component (1.0744 percent), for a total inflation adjustment of 2.0201 percent, and then add one, making 1.020201. We then multiply the base revenue amount for FY 2015 (\$21,600,000) by 1.020201, yielding an inflation adjusted amount of \$22,036,000 (rounded to the nearest thousand dollars).

### C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

A workload adjustment will be calculated to the inflation adjusted fee revenue amount established in ADUFA III for FY 2015 and subsequent fiscal years (21 U.S.C. 379j-12(c)(3)).

FDA calculated the average number of each of the five types of applications and submissions specified in the workload adjustment provision (animal drug applications, supplemental animal drug applications for which data with respect to safety or efficacy are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions) received over the 5-year period that ended on September 30, 2013 (the base years), and the average number of each of these types of applications and submissions over the most recent 5-year period that ended June 30, 2014.

The results of these calculations are presented in the first two columns of Table 4. Column 3 reflects the percent change in workload over the two 5-year periods. Column 4 shows the weighting factor for each type of application, reflecting how much of the total FDA animal drug review workload was accounted for by each type of application or submission in the table during the most recent 5 years. Column 5 is the weighted percent change in each category of workload, and was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. At the bottom right of the table the sum of the

values in column 5 is added, reflecting a total change in workload of -0.47 percent for FY 2015.

This is the workload adjuster for FY 2015.

Table 4.--Workload Adjuster Calculation (numbers may not add due to rounding)

Application Type	Column 1 5-Year Avg. (Base Years)	Column 2 Latest 5-Year Avg.	Column 3 Percent Change	Column 4 Weighting Factor	Column 5 Weighted Percent Change
New Animal Drug Applications (NADAs)	9.80	13.2	35	0.0214	0.74
Supplemental NADAs with Safety or Efficacy Data	9.6	11.4	19	0.0349	0.65
Manufacturing Supplements	361.0	349.6	-3	0.1385	-0.44
Investigational Study Submissions	216.4	211.6	-2	0.6334	-1.41
Investigational Protocol Submissions	133.6	133.4	0	0.1718	-0.03
FY 2015 Workload Adjuster					-0.47

ADUFA specifies that the workload adjuster may not result in fees that are less than the fee revenue amount in the statute (21 U.S.C. 379j-12(c)(3)(C)). Because applying the FY 2015 workload adjuster would result in fees less than the statutory amount, the workload adjustment will not be applied in FY 2015. As a result, the statutory revenue target amount for fees in FY 2015 remains at the inflation adjusted fee revenue amount of \$22,036,000.

#### D. FY 2015 Fee Revenue Amounts

ADUFA III specifies that the revenue amount of \$22,036,000 for FY 2015 is to be divided as follows: 20 percent, or a total of \$4,407,000 (rounded to the nearest thousand dollars), is to come from application fees; 27 percent, or a total of \$5,950,000 (rounded to the nearest thousand dollars), is to come from product fees; 26 percent, or a total of \$5,729,000 (rounded to the nearest thousand dollars), is to come from establishment fees; and 27 percent, or a total of \$5,950,000 (rounded to the nearest thousand dollars), is to come from sponsor fees (21 U.S.C. 379j-12(b)).

### III. Application Fee Calculations for FY 2015

The terms "animal drug application" and "supplemental animal drug application" are defined in section 739 of the FD&C Act (21 U.S.C. 379j-11(1) and (2)).

#### A. Application Fee Revenues and Numbers of Fee-Paying Applications

The application fee must be paid for any animal drug application or supplemental animal drug application that is subject to fees under ADUFA and that is submitted on or after September 1, 2003. The application fees are to be set so that they will generate \$4,407,000 in fee revenue for FY 2015. This is the amount derived in section II.D. The fee for a supplemental animal drug application, for which safety or effectiveness data are required, and for an animal drug application subject to criteria set forth in section 512(d)(4) of the FD&C Act is to be set at 50 percent of the animal drug application fee (21 U.S.C. 379j-12(a)(1)(A)(ii)).

To set animal drug application fees and supplemental animal drug application fees to realize \$4,407,000 FDA must first make some assumptions about the number of fee-paying applications and supplements the Agency will receive in FY 2015.

The Agency knows the number of applications that have been submitted in previous years. That number fluctuates significantly from year to year. In estimating the fee revenue to be generated by animal drug application fees in FY 2015, FDA is assuming that the number of applications that will pay fees in FY 2015 will equal the average number of submissions over the five most recent completed years (FY 2009-FY 2013). This may not fully account for possible year-to-year fluctuations in numbers of fee-paying applications, but FDA believes that this is a reasonable approach after 10 years of experience with this program.

Over the five most recent completed years, the average number of animal drug applications that would have been subject to the full fee was 6.2. Over this same period, the

average number of supplemental applications and applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act that would have been subject to half of the full fee was 9.6.

#### B. Fee Rates for FY 2015

FDA must set the fee rates for FY 2015 so that the estimated 6.2 applications that pay the full fee and the estimated 9.6 supplemental applications and applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act that pay half of the full fee will generate a total of \$4,407,000. To generate this amount, the fee for an animal drug application, rounded to the nearest \$100, will have to be \$400,600, and the fee for a supplemental animal drug application for which safety or effectiveness data are required and for applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act will have to be \$200,300.

### IV. Product Fee Calculations for FY 2015

#### A. Product Fee Revenues and Numbers of Fee-Paying Products

The animal drug product fee (also referred to as the product fee) must be paid annually by the person named as the applicant in a new animal drug application or supplemental new animal drug application for an animal drug product submitted for listing under section 510 of the FD&C Act (21 U.S.C. 360), and who had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003. (See 21 U.S.C. 379j-12(a)(2).) The term "animal drug product" means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an animal drug application or a supplemental animal drug application has been approved (21 U.S.C. 379j-11(3)). The product fees are to be set so that they will generate \$5,950,000 in fee revenue for FY 2015. This is the amount derived in section II.D.



To set animal drug product fees to realize \$5,950,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2015. FDA developed data on all animal drug products that have been submitted for listing under section 510 of the FD&C Act and matched this to the list of all persons who had an animal drug application or supplement pending after September 1, 2003. As of June 2014, FDA estimates that there are a total of 768 products submitted for listing by persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. Based on this, FDA estimates that a total of 768 products will be subject to this fee in FY 2015.

In estimating the fee revenue to be generated by animal drug product fees in FY 2015, FDA is assuming that 4 percent of the products invoiced, or 31, will not pay fees in FY 2015 due to fee waivers and reductions. FDA has reduced the estimate of the percentage of products that will not pay fees from 6 percent to 4 percent this year, based on historical data over the past 5 years. Based on experience with other user fee programs and the first 10 years of ADUFA, FDA believes that this is a reasonable basis for estimating the number of fee-paying products in FY 2015.

Accordingly, the Agency estimates that a total of 737 (768 minus 31) products will be subject to product fees in FY 2015.

#### B. Product Fee Rates for FY 2015

FDA must set the fee rates for FY 2015 so that the estimated 737 products that pay fees will generate a total of \$5,950,000. To generate this amount will require the fee for an animal drug product, rounded to the nearest \$5, to be \$8,075.

## V. Establishment Fee Calculations for FY 2015

### A. Establishment Fee Revenues and Numbers of Fee-Paying Establishments

The animal drug establishment fee (also referred to as the establishment fee) must be paid annually by the person who: (1) Owns or operates, directly or through an affiliate, an animal drug establishment; (2) is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product submitted for listing under section 510 of the FD&C Act; (3) had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003; and (4) whose establishment engaged in the manufacture of the animal drug product during the fiscal year. (See 21 U.S.C. 379j-12(a)(3).) An establishment subject to animal drug establishment fees is assessed only one such fee per fiscal year. (See 21 U.S.C. 379j-12(a)(3).) The term "animal drug establishment" is defined in 21 U.S.C. 379j-11(4). The establishment fees are to be set so that they will generate \$5,729,000 in fee revenue for FY 2015. This is the amount derived in section II.D.

To set animal drug establishment fees to realize \$5,729,000, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2015. FDA developed data on all animal drug establishments and matched this to the list of all persons who had an animal drug application or supplement pending after September 1, 2003. As of June 2014, FDA estimates that there are a total of 62 establishments owned or operated by persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. Based on this, FDA believes that 62 establishments will be subject to this fee in FY 2015.

In estimating the fee revenue to be generated by animal drug establishment fees in FY 2015, FDA is assuming that 12 percent of the establishments invoiced, or 7, will not pay fees in

FY 2015 due to fee waivers and reductions. FDA has kept this estimate at 12 percent this year, based on historical data over the past 5 years. Based on experience with the first 10 years of ADUFA, FDA believes that this is a reasonable basis for estimating the number of fee-paying establishments in FY 2015.

Accordingly, the Agency estimates that a total of 55 establishments (62 minus 7) will be subject to establishment fees in FY 2015.

#### B. Establishment Fee Rates for FY 2015

FDA must set the fee rates for FY 2015 so that the estimated 55 establishments that pay fees will generate a total of \$5,729,000. To generate this amount will require the fee for an animal drug establishment, rounded to the nearest \$50, to be \$104,150.

### VI. Sponsor Fee Calculations for FY 2015

#### A. Sponsor Fee Revenues and Numbers of Fee-Paying Sponsors

The animal drug sponsor fee (also referred to as the sponsor fee) must be paid annually by each person who: (1) Is named as the applicant in an animal drug application, except for an approved application for which all subject products have been removed from listing under section 510 of the FD&C Act, or has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive and (2) had an animal drug application, supplemental animal drug application, or investigational animal drug submission pending at FDA after September 1, 2003. (See 21 U.S.C. 379j-11(6) and 379j-12(a)(4).) An animal drug sponsor is subject to only one such fee each fiscal year. (See 21 U.S.C. 379j-12(a)(4).) The sponsor fees are to be set so that they will generate \$5,950,000 in fee revenue for FY 2015. This is the amount derived in section II.D.

To set animal drug sponsor fees to realize \$5,950,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2015. Based on the number of firms that would have met this definition in each of the past 10 years, FDA estimates that a total of 179 sponsors will meet this definition in FY 2015.

Careful review indicates that 33 percent of these sponsors will qualify for minor use/minor species waiver or reduction (21 U.S.C. 379j-12(d)(1)(D)). Based on the Agency's experience to date with sponsor fees, FDA's current best estimate is that an additional 32 percent will qualify for other waivers or reductions, for a total of 65 percent of the sponsors invoiced, or 116, who will not pay fees in FY 2015 due to fee waivers and reductions. FDA has kept this estimate at 65 percent this year, based on historical data over the past 5 years. FDA believes that this is a reasonable basis for estimating the number of fee-paying sponsors in FY 2015.

Accordingly, the Agency estimates that a total of 63 sponsors (179 minus 116) will be subject to and pay sponsor fees in FY 2015.

#### B. Sponsor Fee Rates for FY 2015

FDA must set the fee rates for FY 2015 so that the estimated 63 sponsors that pay fees will generate a total of \$5,950,000. To generate this amount will require the fee for an animal drug sponsor, rounded to the nearest \$50, to be \$94,450.

#### VII. Fee Schedule for FY 2015

The fee rates for FY 2015 are summarized in Table 5.

Table 5.--FY 2015 Fee Rates

Animal Drug User Fee Category	Fee Rate for FY 2015
Animal Drug Application Fees:	
Animal Drug Application	\$400,600
Supplemental Animal Drug Application for which Safety or Effectiveness Data are Required or Animal Drug Application Subject to the Criteria Set Forth in Section 512(d)(4) of the FD&C Act	\$200,300
Animal Drug Product Fee	\$8,075
Animal Drug Establishment Fee <sup>1</sup>	\$104,150
Animal Drug Sponsor Fee <sup>2</sup>	\$94,450

<sup>1</sup>An animal drug establishment is subject to only one such fee each fiscal year.

<sup>2</sup>An animal drug sponsor is subject to only one such fee each fiscal year.

## VIII. Procedures for Paying the FY 2015 Fees

### A. Application Fees and Payment Instructions

The appropriate application fee established in the new fee schedule must be paid for an animal drug application or supplement subject to fees under ADUFA that is submitted on or after October 1, 2014. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration, by wire transfer, or electronically using <http://www.pay.gov>. (The Pay.gov payment option is available to you after you submit a cover sheet. Click the "Pay Now" button.) On your check, bank draft, or U.S. postal money order, please write your application's unique Payment Identification Number (PIN), beginning with the letters "AD", from the upper right-hand corner of your completed Animal Drug User Fee Cover Sheet. Also write the FDA post office box number (P.O. Box 979033) on the enclosed check, bank draft, or money order. Your payment and a copy of the completed Animal Drug User Fee Cover Sheet can be mailed to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197-9000.

If payment is made by wire transfer, send payment to: U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, FDA Deposit Account Number: 75060099, U.S. Department of Treasury routing/transit number: 021030004, SWIFT Number: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., Silver Spring, MD 20993-0002. You are

responsible for any administrative costs associated with the processing of a wire transfer. Contact your bank or financial institution about the fee and add it to your payment to ensure that your fee is fully paid.

If you prefer to send a check by a courier, the courier may deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery contact the U.S. Bank at 314-418-4013. This telephone number is only for questions about courier delivery.)

The tax identification number of FDA is 53-0196965. (Note: In no case should the payment for the fee be submitted to FDA with the application.)

It is helpful if the fee arrives at the bank at least a day or two before the application arrives at FDA's CVM. FDA records the official application receipt date as the later of the following: The date the application was received by FDA's CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Treasury notifies FDA of receipt of an electronic or wire transfer payment. U.S. Bank and the U.S. Treasury are required to notify FDA within 1 working day, using the PIN described previously.

#### B. Application Cover Sheet Procedures

Step One--Create a user account and password. Log on to the ADUFA Web site at <http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm> and, under Tools and Resources, click "The Animal Drug User Fee Cover Sheet" and then click "Create ADUFA User Fee Cover Sheet." For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be

required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two--Create an Animal Drug User Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Drug User Fee Cover Sheet. One cover sheet is needed for each animal drug application or supplement. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique PIN.

Step Three--Send the payment for your application as described in section VIII.A.

Step Four--Please submit your application and a copy of the completed Animal Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV-199), 7500 Standish Pl., Rockville, MD 20855.

#### C. Product, Establishment, and Sponsor Fees

By December 31, 2014, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2015 using this fee schedule. Payment will be due by January 31, 2015. FDA will issue invoices in November 2015 for any products, establishments, and sponsors subject to fees for FY 2015 that qualify for fees after the December 2014 billing.

Dated: July 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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